

September 24, 1999

10999

The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street S.W. Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statement:

(1) Arginex is a product formulated to support the cleansing ability of the kidneys.*

This statement is made for a dietary supplement containing a proprietary blend of dried buckwheat juice, buckwheat (seed), dried pea (vine) juice, oat flour, bovine liver, beet (root), extract of *Rhizopus oryzae* grown on *Tillandsia usneoides* and beet (root), dried beet (leaf) juice, and ascorbic acid. Other ingredients include honey, calcium stearate, vitamin A palmitate, and gelatin. And the name of the product is Arginex®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

Jun M. Holden

975 - 0162

LET 4305